UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

GREGORIA GRIJALVA, et al., as individuals and as representatives of a class of persons similarly situated,

Plaintiffs,

v.

DONNA E. SHALALA, Secretary of the Department of Health and Human Services,

Defendant.

CIV 93-711 TUC ACM

ORDER RE: CLASS ACTION SETTLEMENT AGREEMENT

WHEREAS THE COURT FINDS AS FOLLOWS:

The parties to this action, a nationwide class action challenging, inter alia, Medicare's notice and appeal procedures for enrollees in Medicare managed care organizations, submitted a proposed settlement to the Court on August 9, 2000. Pursuant to this Court's Order, notice of the proposed settlement was provided to the plaintiff class through publication in five national publications, as well as publication of the settlement agreement on the Internet web site of the Medicare program. The notice invited objections to the proposed settlement, and approximately 25 objection letters were received by the Court. On October 27, 2000, the Court held an open hearing on the settlement, and invited anyone present who wished to speak to the settlement to do so. No one addressed the Court in response to that invitation.

Subsequent to the hearing, the Court issued an order seeking answers to four questions regarding the proposed settlement, and ordering the parties to review the public comments filed in the case and to provide information pertaining to the Settlement Agreement in the instances where the comments reflected that such information was desired by the correspondent. In their joint response to the Court's questions, counsel for the parties answered the Court's questions and plaintiffs' counsel certified that she had provided information to public commenters who had requested it.

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Rule 23(e) of the Federal Rules of Civil Procedure requires court approval of any settlement of a class action. In evaluating settlement agreements under Rule 23(e), a district court must determine whether the settlement is "fundamentally fair, adequate and reasonable." Officers for Justice v. Civil Service Commission, 688 F.2d 615, 624 (9th Cir. 1982). Based on the record in this case, its procedural history, the strengths and weaknesses of the parties' claims and defenses, and the breadth and nature of the proposed settlement, the Court concludes that the proposed settlement meets that standard.

With regard to the objections to the proposed settlement filed with the Court, the Court finds that the majority involved generalized concerns with the Medicare program, the Medicare Plus Choice program, or the health system generally that are not related to the claims plaintiffs advanced in the case, or to the proposed settlement. A minority of objectors argued that four days notice prior to termination of provider services was not enough time for M+CO enrollees to make alternative health care arrangements. The Court finds that the proposed settlement agreement's requirement that a Notice of Proposed Rulemaking ("NPRM") be promulgated requiring M+COs to provide four days notice prior to termination of provider services is, in the context of the overall proposed settlement, a fair and reasonable balance between the interests of the two parties. Further, the Court notes that all members of the public will have an opportunity to comment on the NPRM when it is published, and suggestions regarding the length of time between notice and termination of services may be made in that context, as well.

IT IS HEREBY ORDERED THAT:

1. The Settlement Agreement between the parties dated August 9, 2000, incorporated herein by this reference, is hereby approved.

2. All claims raised in the Complaint or otherwise raised at any stage of this litigation or its appeal are dismissed with prejudice except (A) claims for which relief would be provided by implementation of the notice and appeal procedures described in part B of the Settlement Agreement; and (B) claims regarding the adequacy of notice provided in the case of a reduction in services, which shall be dismissed without prejudice; and (C) claims regarding defendant's alleged failure to enforce M+COs' obligation to provide coverage of the full range of Medicare covered services,

which shall be dismissed without prejudice.

3. All claims regarding the adequacy of notice provided where the M+CO has decided that a reduction in covered services is warranted, and all claims regarding the defendant's alleged failure to enforce M+COs' obligation to provide coverage of the full range of Medicare covered services, are dismissed without prejudice.

4. Any claims for which relief would be provided by implementation of the notice and appeal procedures described in part B of this settlement agreement are stayed until 30 days after the date of promulgation of any Final Rule relating to fast track review of M+CO decisions to terminate provider services to an enrollee, or until December 31, 2002 if no Final Rule has been promulgated by that date. If plaintiffs have not filed an appropriate pleading to bring before the Court claims for which relief would be provided by implementation of the notice and appeal procedures described in part B of this settlement agreement at the expiration of this stay, all remaining claims will be dismissed with prejudice.

DATED this 4 day of Dec, 2000.

Honorable Alfredo C. Marquez
Senior U.S. District Judge

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on November 29, 2000 s/he caused copies of the foregoing NOTICE OF FILING PROPOSED ORDER RE: CLASS ACTION SETTLEMENT AGREEMENT to be sent by first class mail to:

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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

GREGORIA GRIJALVA, et al., as individuals and as representatives of a class of persons similarly situated,

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v.

DONNA E. SHALALA, Secretary of the Department of Health and Human Services,

Defendant.

CIV 93-711 TUC ACM

NOTICE OF FILING SETTLEMENT AGREEMENT

Please take notice that the parties have reached a Settlement Agreement in this case. A copy of the Settlement Agreement is attached hereto.

Dated: August 9, 2000

Respectfully submitted,

Sally Hart

By SALLY HART
Center For Medicare Advocacy, Inc.

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Settlement Agreement
Grijalva, et al. v. Shalala, CIV 93-711 TUC ACM (D. Ariz.)

The parties to this Settlement Agreement, Donna E. Shalala, in her official capacity as Secretary, U.S. Department of Health and Human Services, and Gregoria Grijalva et al., on behalf of a class of individuals similarly situated and certified by the court in its Order of July 14, 1995, by and through their undersigned counsel, in the interest of resolving the lawsuit Gregoria Grijalva, et al. v. Shalala, Civ. Action No. 93-711-TUC (D. Ariz.), hereby, in consideration of the mutual promises contained herein, the receipt and sufficiency of which are acknowledged, agree to the following in settlement of this matter[1]:

A. **Definitions.** Terms that are not specifically defined in this document shall have the meanings assigned to them in the Medicare Act, 42 U.S.C. § 1395 et seq. For the purposes of this settlement agreement only, the following terms used herein are defined as follows:

1. Provider – a skilled nursing facility (SNF), home health agency (HHA), or comprehensive outpatient rehabilitation facility (CORF).

2. Enrollee – a Medicare+Choice (M+C)-eligible individual who has elected and enrolled in an M+C plan offered by an M+C organization (M+CO).

3. Authorized Representative – a person named and authorized to act on the enrollee's behalf in any proceeding or communication relating to the Medicare appeals process under 42 C.F.R. part 422, subpart M, or the enrollee's legal guardian, attorney, or other person or entity authorized under state or local law to act on the enrollee's behalf in any proceeding or communication relating to the Medicare appeals process.

4. Termination – the discontinuation or discharge of an enrollee from covered provider services where the

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[1] A number of changes have already been made in the notice and appeals processes for Medicare managed care plans since March 3, 1997, which have resolved some of the plaintiffs' concerns.

enrollee has been authorized by the M+CO to receive an ongoing course of treatment from that provider. Termination includes cessation of coverage at the end of a course of treatment 'preauthorized' in a discrete increment.

5. Day(s) — Unless otherwise indicated, the word "day" or "days" refers to calendar day(s) and not business or working day(s).

B. **Notice of Proposed Rulemaking — Independent Fast Track Review of M+CO Decisions to Terminate Provider Services**

1. Defendant agrees to promulgate a Notice of Proposed Rulemaking (NPRM) addressing notice and appeal procedures for M+CO decisions to terminate coverage for provider services to an enrollee. The NPRM will set forth the following proposed procedures and requirements to supplement existing notice and appeal requirements for M+COs:

a. **Notices**

i. **advance written notice of termination** — For enrollees receiving provider services, M+COs would be required to provide to them or their authorized representatives written notice of a decision to terminate such covered service four days in advance of termination.

ii. **standardized notice** — The termination notice for provider services would be standardized. The content of a proposed notice would be developed in accordance with existing federal rules and policies relating to requesting public input and advice.

iii. **contents of termination notice** — The termination notice would contain:

-- a specific and detailed explanation why

services either are no longer medically necessary, or are no longer covered;

-- the Medicare coverage rule, if applicable, and/or other M+CO policy or reason upon which the decision is based, with applicable citations to the Medicare coverage rules or instructions about how to obtain them from the M+CO;

-- facts specific to the enrollee and relevant to the coverage determination that are sufficient to advise the enrollee of the applicability of the coverage rule or policy to his/her case;

-- a description of the fast-track Independent Review Entity (IRE) appeals process, and the existence of an enrollee right (but not obligation) to submit evidence showing that his/her services should continue.

iv. **delivery** – The written notice of termination of services must be delivered to the enrollee or authorized representative in the same manner, and with the same requirements, established for the delivery of Medicare's Home Health Agency Advanced Beneficiary Notice (See Program Memoranda A-99-52 and A-99-54; 42 C.F.R. 484.10(c) & (e)). Notice would be considered given upon the enrollee's (or authorized representative's) receipt of such notice.

b. **Appeals** – The NPRM will set forth a new fast track independent review process for M+COs' decisions to terminate provider services. Under that process, an enrollee who wishes to appeal an M+CO's termination decision must file an oral or written request for an expedited appeal by an Independent Review Entity (IRE) by noon of the day following receipt of the notice that services will terminate. In the case of

an emergency where the IRE is closed on the day the enrollee requests an expedited appeal, the request can be filed by noon of the next day that the IRE office is open. Covered provider services would continue until noon on the day after the enrollee or authorized representative receives notice of the IRE's final decision, or until the date and time designated in the notice for termination of services, whichever is later.

i. **burden of production/burden of proof** – When an enrollee appeals an M+CO's decision to terminate provider services to an IRE, the burden is on the M+CO to prove that termination of coverage is the correct decision, either on the basis of medical necessity or of other Medicare coverage policies. The M+CO would be required to supply any and all information that the IRE would require to sustain the M+CO's termination decision. The enrollee is under no obligation to gather evidence to submit to the IRE in support of the enrollee's appeal; however, the enrollee may be required to authorize access to medical records in order to pursue the appeal.

ii. **IRE contact with enrollee** – Notwithstanding the burden of production outlined in B(1)(b)(i) above, the IRE would be required to solicit the enrollee's (or authorized representative's) views regarding the reason(s) for termination of services specified on the written termination notice provided by the M+CO as part of the IRE's decision making process and before rendering its final decision. The IRE would also be required to solicit the views of the enrollee (or authorized representative) regarding any reason other than the reason(s) specified on the written notice if the IRE intends to use this reason as the basis for its review determination. The enrollee will have the right to submit evidence to be considered

by the IRE in making its decision.

iii. **IRE review of termination notices** — When an enrollee elects to do a fast track appeal of a termination decision, the IRE would review the notice of termination from which the enrollee is appealing to ensure that the M+CO gave the enrollee or authorized representative proper notice. Notices that do not include mandatory language, are not in the mandatory format, are untimely, or are not provided at all, would constitute improper notification to the enrollee. If the IRE finds that the M+CO failed to give proper notice, the M+CO would be required to continue services until a proper notice has been received by the enrollee or authorized representative and the enrollee has had the opportunity to appeal the termination decision to the IRE. Continuation of provider services would not be required in these circumstances, however, if the IRE finds that continuation could pose a threat to the enrollee's health or safety. The IRE shall forward to HCFA information about every case in which proper termination notice was not given.

iv. **enrollee access to documentation** — As part of a request for an appeal, an enrollee or authorized representative would be permitted to request a copy of the documentation that was, or would be, sent to the IRE. If the enrollee or authorized representative requests it, the M+CO would be required to provide such a copy no later than the end of the first full day immediately following the day the material is requested.

v. **termination of "preauthorized" course of treatment** — A course of treatment for a continuing spell of illness or medical condition that has been "preauthorized" by an

M+CO in a discrete increment would be considered terminated whenever coverage for the services ceases, including when it comes to its "preauthorized" end, and is subject to the same notice and appeal procedures as a course of treatment that has not been "preauthorized."

c. **Continuation of Coverage if No IRE Appeal** – If the enrollee elects not to appeal the M+CO's termination decision through the IRE procedure, Medicare coverage would continue for four days after the date that the termination notice was received by the enrollee or authorized representative, or the date designated for termination in the notice, whichever date is later.

d. **Availability of Other Appeal Processes**

i. **if no appeal to IRE** – If an enrollee fails to meet the noon deadline to utilize the IRE appeal process, then such enrollee would be permitted to seek review of the M+CO's termination decision using any and all appeal processes otherwise available under 42 U.S.C. § 1395w-22(g) and 42 C.F.R., part 422, subpart M. Under those non-IRE appeals processes, the enrollee will not have a right to continued coverage for services during the pendency of the appeal. If the enrollee continues to receive services during this period and prevails on appeal, the M+CO would be required to reimburse the enrollee for the costs of those services for which the enrollee has already paid the M+CO or other provider.

ii. **if unsuccessful appeal to IRE** – If an enrollee utilizes the IRE appeal process, and is unsuccessful in the appeal, the enrollee may request a reconsideration from the IRE. The enrollee would be permitted to appeal the IRE's reconsidered determination to an Administrative Law Judge, pursuant to 42 C.F.R. § 422.600 et

seq. The enrollee would not be entitled to reconsideration of the M+CO decision under 42 C.F.R. §§ 422.578 through 422.596.

2. **Proposed Procedure and Forms Subject to Notice and Comment** — The proposed fast track appeal for M+CO terminations of provider services will be subject to notice and comment procedures as required by the Administrative Procedure Act, 5 U.S.C. § 553, and 42 U.S.C. § 1395hh. The proposed standardized termination notice will be subject to notice and comment procedures under the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq. Nothing in this Agreement shall be construed as a promise or predetermination regarding the content of a final rule or mandatory form, if any, on notice and appeal procedures for M+CO decisions to terminate provider services.

3. **Solicitation of Comments on Notice and Appeal Procedures for Reductions** — In the NPRM proposing new notice and appeal procedures for M+CO decisions to terminate provider services described above, defendant will solicit comments on how to provide new notice and appeal procedures for M+CO decisions to reduce, while not terminating altogether, provider services.

4. **Timing of NPRM** — Defendant will make best efforts to publish the NPRM in the Federal Register on or before December 31, 2000.

5. **Civil Monetary Penalties for Noncompliance** — Defendant will include in the preamble of the NPRM a statement explaining that the requirements set forth in the NPRM, or any new or modified requirements developed after analysis of comments on the NPRM received during the rulemaking process, will, when finalized, be codified in 42 C.F.R. part 422 subpart M, and therefore a violation of the requirements would be subject to defendant's existing intermediate sanction and civil monetary penalty authority (42 U.S.C. § 1395w-27(g) and 42 C.F.R. part 422, subpart O).

C. **Notice and Appeal Enforcement Mechanisms**

1. **Civil Monetary Penalties/Intermediate Sanctions** — Defendant will issue guidance clarifying that an M+CO's failure to comply with notice or appeal procedures in only one or two cases could constitute a "substantial failure" to comply with grievance and appeal requirements for purposes of imposing sanctions under 42 C.F.R. §§ 422.510(a)(6), 422.752(b) and 422.758, depending on seriousness (i.e., degree of risk to health it poses) and/or severity (i.e., magnitude) of the violation(s).

2. **Monitoring Strategies**

   a. **Analysis of CAHPS data** — Using data from the Consumer Assessment of Health Plans Surveys (CAHPS), defendant will develop a formula to identify M+COs that should undergo a focused review of their compliance with notice and appeal requirements.

   b. **Analysis of data from proposed disenrollment survey** — Defendant will develop an M+CO disenrollment survey, and, using data it expects to acquire through that survey, defendant will devise a formula to identify M+COs that should undergo a focused review of their compliance with notice and appeal requirements.

   c. **New survey questions** — Defendant will propose, subject to Paperwork Reduction Act approval, the inclusion of questions in both the current enrollment CAHPS and the new disenrollment CAHPS that specifically address enrollee knowledge about appeal rights and the appeals process; whether the enrollee ever was denied care; whether the enrollee was given written notice of the right to file a formal complaint (that is, appeal such a denial of care) and whether the enrollee ever filed a complaint with his/her M+CO.

   Because these questions are new, Defendant will assess the quality of data collected from these questions and their effect on response rates through

12/31/2001. Based on this assessment, Defendant may make changes in the survey questions if warranted.

3. **Focused Review** – If, based on application of the formulas described in 2(a) or (b), as well as information about inadequate notices forwarded from the IREs pursuant to Part B, Paragraph 1.b.iii. above, and complaints received directly from enrollees, HCFA determines that an M+CO should undergo a focused review to determine its compliance with appeal rights and notice requirements, HCFA will examine operational areas of the M+CO that are likely to produce evidence of noncompliance with these requirements, including claims processing, quality assurance, utilization management functions, and appeals functions.

D. **Automatic Expedited Review with Physician Justification** – Defendant will issue guidance clarifying that, to implement the existing standard for granting expedited review, (1) M+COs must notify enrollees in their annual instructions/notices that an enrollee is automatically entitled under 42 C.F.R. § 422.570(c)(2)(ii) to an expedited organization determination, and under 42 C.F.R. § 422.584(c)(2)(ii) to expedited review of an M+CO decision to deny, reduce or terminate a Medicare-covered service if the enrollee timely submits a statement from a physician that the standard for expedited review has been met; and (2) if a request for expedited review is rejected by the M+CO, the M+CO must again notify the enrollee that the enrollee would be permitted to resubmit a request for expedited review, and would be automatically entitled to expedited review, if the request includes a statement from a physician that the standard for expedited review has been met.

E. **Enrollee Access to Evidence**

1. Defendant will issue guidance clarifying that M+COs should include notice of the enrollee right of access to his/her case file, see 42 C.F.R. § 422.118(c), in its marketing materials (e.g., in the initial and annual updates of the evidence of coverage).

2. Defendant will ensure that the Medicare & You handbook will contain appropriate information about where enrollees

can learn how to obtain access to their case files.

F. **Timing of Implementation of Parts C.1, D, and E** - Defendant will make best efforts to implement Parts C.1., D, and E on or before June 30, 2001.

G. **Notification to Plaintiffs of Modification** – Defendant retains her authority to modify forms, regulations, rules, requirements, or procedures that are implemented as a result of this settlement agreement to the extent permitted by law. Defendant agrees to notify plaintiffs, through counsel, upon implementation of any significant modification that relates directly to a term of this settlement agreement if such modification occurs within 2 years after the date of execution of this settlement agreement.

H. **Attorneys Fees** – For purposes of this agreement, defendant agrees that plaintiffs are entitled to reasonable attorneys fees for legal work performed on their behalf in furtherance of their claims in this litigation to the extent permitted by law.

1. The parties will attempt to reach agreement regarding the amount of attorneys fees plaintiffs are entitled to receive.

2. If, after good faith efforts to reach agreement regarding the amount of attorneys fees, the parties agree that they cannot reach such agreement, plaintiffs may file a petition to determine the amount of such attorneys fees before the District Court.

I. **Enforcement of Settlement Agreement** – The parties will attempt to resolve, by negotiation among counsel, any disputes arising under this agreement. If negotiation fails, neither party will seek to enforce this settlement agreement in Court until 30 days after counsel for the complaining party has contacted opposing counsel in writing, stating the specific basis for the complaining party's belief that a violation of this agreement has occurred.

J. **Dismissals/Stay of Claims**

1. Immediately upon approval and execution of this settlement agreement, counsel for the parties will file a joint motion requesting dismissal, with prejudice, of all claims raised in the Complaint or otherwise raised at any stage of this litigation or its appeal, except (1) claims for which relief would be provided by implementation of the notice and appeal procedures described in part B of this settlement agreement; and (2) claims regarding the adequacy of notice provided in the case of a reduction in services, which shall be dismissed without prejudice; and (3) claims regarding defendant's alleged failure to enforce M+COs' obligation to provide coverage of the full range of Medicare covered services, which shall be dismissed without prejudice.

2. For claims that are dismissed with prejudice, individuals in the class, and their heirs and assigns, shall be barred and enjoined forever from prosecuting any claims or causes of action that have been asserted by reason of, or with respect to, or in connection with, any of the matters alleged in this action. Nothing in this Agreement, however, shall prevent any class member from pursuing an individual administrative appeal, a request for reopening, or a judicial appeal, or from asserting that a legal standard was not applied, or was improperly applied, in his or her individual case.

3. The defendant, her successors, and any department, agency, or establishment of the United States and any officers, employees, agents, or successors of any such department, agency, or establishment, are hereby discharged and released from any claims and causes of action that are due to be dismissed with prejudice pursuant to J(1) above.

4. Also immediately upon approval and execution of this settlement agreement, counsel for the parties will file a joint motion requesting dismissal, without prejudice, of all claims regarding (1) the adequacy of notice provided where the M+CO has decided that a reduction in covered services is warranted, and (2) defendant's alleged failure to enforce M+COs' obligation to provide coverage of the full range of Medicare covered services.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 9, 2000 s/he caused copies of the foregoing NOTICE OF FILING SETTLEMENT AGREEMENT to be sent by first class mail to:

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By Bonnie L. Bauer